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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,374	02/06/2004	Benjamin Gaston	28195-503 CON	6783

35437 7590 04/12/2005

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/772,374

Applicant(s)

GASTON ET AL

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

CLAIMS 1 AND 9 ARE PRESENTED FOR EXAMINATION

Applicant's Amendment and Response and Terminal Disclaimer filed January 10, 2005 has been received and entered into the application. Accordingly, the specification at page 1 has been amended.

In view of the above amendment and the acceptable nature of the Terminal Disclaimer, the objection to the specification and claim rejections under the judicially created doctrine of obviousness-type double patenting, as set forth in the previous Office action dated October 8, 2004 at pages 2-4, are withdrawn.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating cystic fibrosis wherein an amount of ethyl nitrite is administered to *lessen* accumulation of mucus, bronchoconstriction and bacterial growth, does not reasonably provide enablement for a method of treating cystic fibrosis wherein an amount of ethyl nitrite is administered to *prevent* accumulation of mucus, bronchoconstriction and bacterial growth. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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The terms “prevent” and “prevention” are here, unlike in the previous Office action, interpreted to mean that the accumulation of mucus, bronchoconstriction and bacterial growth are kept from occurring to *any* degree. While it is noted that “prevent” and “prevention” do not necessarily equate to such an interpretation, the Examiner’s interpretation is broad and reasonable and thus consistent the MPEP § 2111.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First

Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that accumulation of mucus, bronchoconstriction and bacterial growth could be kept from ever occurring is doubted because the terms or “prevent” and “prevention” are synonymous with the term “curing” and both circumscribe methods of absolute success. Because absolute success is not reasonably possible with most diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as a degenerative disease/disorder, including such pathological events as mucus accumulation, bronchoconstriction and bacterial growth, the specification, which lacks an objective showing that mucus can be kept from ever accumulating, the airways may be kept from ever constricting and the growth of bacterial can be kept from ever

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occurring, is viewed as lacking an enabling disclosure of the same.

Concerning the state of the art of the treatment of cystic fibrosis, the disease appears to be characterized by recurrent episodes of respiratory tract infections which involves mucus accumulation, bronchoconstriction and bacterial growth (see Cecil, Textbook of Medicine, newly cited by the Examiner, page 402, col. 2, under the heading "Clinical Manifestations" to page 403, col. 1, line 5 and page 404, col. 1 under the heading "Course of the Disease"). While treatment means are known for cystic fibrosis (see page 404, col. 1, under the heading "Treatment" to page 406, col. 1, just above the heading "Prognosis"), such treatments are for the amelioration, i.e., improvement, of the symptomology, no treatment is mention that is capable of actually preventing the symptoms of cystic fibrosis.

Summary

As the cited art and discussion above establish, practicing the claimed method in the manner disclosed by Applicants would not imbue the skilled artisan with a reasonable expectation that the prevention of the claimed aspects of cystic fibrosis could be achieved. In order to actually achieve such prevention, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize, and Applicants have failed to demonstrate, that accumulation of mucus, bronchoconstriction and bacterial growth could be kept from ever occurring, i.e. to *any* degree, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claim 9 is deemed properly rejected.

Overcoming the Above Rejection

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The Examiner recommends that Applicant amend the following section of claim 9, i.e., lines 3-5, in the following manner in order to overcome the present rejection:

---...amount effective to ~~prevent~~ lessen accumulation of mucus, bronchoconstriction and bacterial growth in the CF airway, ~~as preventive therapy~~, or an amount to ameliorate bronchoconstriction, mucus plugging and/or bacterial bronchitis/bronchiolitis, as acute therapy...---

Support for the term “lessen” is found in the term “ameliorate” as employed in claim 9. While “lessen” is not expressly stated, it is nevertheless believed that the concept of lessening would have been present in the specification as originally filed because the term “ameliorate” normally means “to make better or improve” and “lessening” is a concept that is consistent therewith.

Allowable Subject Matter

Claim 1 is no longer subject to rejection under the judicially created doctrine of obviousness-type double patenting and thus is in condition for allowance.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J. Henley III
Primary Examiner
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April 7, 2005